TECH CENTER 1600/2900

Sheet

Duplicate

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Supplicate for form 1449A/PTO

## ∰NFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Application Number** 09/867,693 May 31, 2001 Filing Date First Named Inventor Cooper, et al. Group Art Unit 1646

(use as many sheets as necessary)

of 3

**Examiner Name** Unassigned

Complete if Known

003659.00009 Attorney Docket Number

**U.S. PATENT DOCUMENTS** Name of Patentee or Applicant of **Document Number Publication Date** Pages, Columns, Lines, Where Relevant Examine Cite Cited Document MM-DD-YYYY Passages or Relevant Figures Appear Number - Kind Code<sup>2</sup> (if known) BV. Kabanov, et al. .US-5,656,611 08-12-1997<sup>.</sup>

		FOREIGN I	PATENT DOCU	MENTS		
	<u> </u>	Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	Cite No.1	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	т°
		EP 1031626	08-30-2001	Erbacher, et al.		
1		WO 9730731	08-28-1997	Lollo, et al.		
(		WO 9846274	10-28-1998	Burgess, et al.		
V						
				····		
<del></del>						

Examiner Signature	Doh	Date Considered	1/7/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional) . 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

FEB 18 7CF, JULY S

SA TEMES OF THE 1449A/PTO

PTO/SB/08B(10-01)
Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE of Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known

Application Number 09/867,693

Filing Date May 31, 2001

First Named Inventor Cooper, et al.

Group Art Unit 1646

Examiner Name Unassigned

Attorney Docket Number 003659.00009

(use as many sheets as necessary)
Sheet 2 of 3

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of Cite the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue Examiner No. Initials \* number(s), publisher, city and/or country where published. Aberle, et al., "The counterion influence on cationic lipid-mediated transfection of plasmid DNA", Biochemica et Biophysica Acta, 1996, pages 281-283, Elsevier Science B.V. Allison, et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", Journal of Pharmaceutical Sciences, 2000, pages 682-691, vol. 89, no. 5, Wiley-Liss, Inc., & American Pharmaceutical Association. Choi, et al., "Lactose-Poly (ethylene Glycol)-Grafted Poly-L-Lysine as Hepatoma Cell-Targeted Gene Carrier", Bioconjugate Chem., 1998, pages 708-718, vol. 9, Amerian Chemical Society. Cortesi, et al., "Effecy of DNA Complexion and Freeze-Drying on the Physicochemical Characteristics of Cationic Liposomes", Antisense & Nucleic Drug Development, 2000, pages 205-215, vol. 10, Mary Ann Liebert, Inc. Katavose, et al., "Remarkable Increase in Nuclease Resistance of Plasma DNA through Supramolecular Assembly with Poly (ethylene glycol)-Poly (L-lysine)", Journal of Pharmaceutical Sciences, 1998, vol. 87, no. 2, American Chemical Society and American Pharmaceutical Katayose, et al., "Water-Soluble Polyion Complex Associates of DNA and Poly (ethylene glycol)-Poly (L-lysine) Block Copolymer", Bioconjugate Chem., 1997, pages 702-707, American Chemical Society. Kilcher, et al., "Influence of the DNA Complexation Medium on the Transfection Efficiency of Lipospermine/DNA Particles", Gene Therapy, 1998, pages 855-860, vol. 5, MacMillan Press LTD., Basingstoke, Great Britain. Kwok, et al., "Strategies for Maintaining the Particle Size of Peptide DNA Condensates Following Freeze-Drving", International Journal of Pharmaceutics, 2000, pages 81-88, vol. 203, no. 1-2, Elsevier Science B.V. Li, et al., "Lyophilization of Cationic Lipid-Protamine-DNA (LPD) Complexes", Journal of Pharmaceutical Sciences, 2000, pages 355-364, vol. 89, no. 3, Wiley-Liss, Inc., & American Pharmaceutical Association. Noel, et al., "High Compacted DNA - Polymer Complexes Via New Polynorbornene Polycationic Latexes With Acetate Counterion", SCISEARCH Database, 2000, pages 8980-8983, vol. 16, no. 23, American Chemical Society, Washington, D.C. Poxon, et al., "The Effect of Lyophilization on Plasmid DNA Activity", Pharmaceutical and Development Technology, 2000, pages 115-122, vol. 5, no. 1, Marcel Dekker, Inc.

Examiner Signature	Dah	Date Considered	1/7/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

18	ENCAL	
(O)	18 July 35	
1 40	Underthe Paperwork Red	ucti

PTO/SB/08B(10-01) Approved for use through 10/31/2002. OMB 0651-0031

	ripprovod ret doo amought rore.	
U.	.S. Patent and Trademark Office: U.S. DEPART	MENT OF COMMERCE
on Act of 1995, no persons are required to re	espond to a collection of information unless it contains a	a valid OMB control number

Substitute t	1449A/PTO	,				Complete if Kn	own	1
			NOM A TION	Application N	umber	09/867,693		
	EMENTAL I			Filing Date		May 31, 2001	V	금
DISCLOSURE STATEMENT BY APPLICANT				First Named	Inventor	Cooper, et al.	<u> </u>	2
APPLI	CANI			Group Art Un	it	1646	<u> </u>	こっ
(	use as many she	ets as	necessary)	Examiner Na	me	Unassigned	<u></u>	Ď
Sheet	3	of	3	Attorney Doc	ket Number	003659.00009	) -	7

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	66
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1600/2900
0		Toncheva, et al., "Novel vectors for gene delivery formed by self-assembly of DNA with poly (L-lysine) grafted with hydrophilic polymers", Biochemica et Biophysica Acta, 1998, pages 354-368, Elsevier Science B.V.	
W/		Vinogradov, et al., "Self-Assembly of Polyamine-Poly (ethylene glycol) Copolymers with Phosphorothicate Oligonucleotides", Bioconjugate Chem., 1998, pages 805-812, vol. 9, American Chemical Society.	

Examiner Signature	Pall	~	Date Considered	117	100
Olgitatare	700		Oonsidered	1 1 7	$10  \zeta$

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known

Application Number 09/867,693

Filing Date May 31, 2001

First Named Inventor Mark J. Cooper

Group Art Unit NOT YET ASSIGNED

Examiner Name NOT YET ASSIGNED

Attorney Docket Number 03659.00009

(use as many sheets as necessary)

SEP 2 0 2001 ...

-7			
examiner nitials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
D^		ABERLE et al., The counterion influence on cationic lipid-mediated transfection of plasmid DNA, Biochimica et Biophysica Acta, 1996, 1299:281-283.	
		VINOGRADOV et al., Self-Assembly of Polyamine-Poly(ethylene glycol) Copolymers with Phosphorothioate Oligonucleotides, Bioconjugate Chem., 1998, Vol. 9, No. 6, 805-812.	
		TONCHEVA et al., Novel vectors for gene delivery formed by self-assembly of DNA with poly_L-lysine) grafted with hydrophilic polymers, Biochimica et Biophysica Acta, 1998, 1380:354-368.	
		CHOI et al., Lactose-Poly(ethylene Glycol)-Grafted Poly-L-Lysine as Hepatoma Cell-Targeted Gene Carrier, Bioconjugate Chem., 1998, Vol. 9, No. 6, 708-718.	
		KATAYOSE et al., Water-Soluble Polyion Complex Associates of DNA and Poly(ethylene glycol)-Poly(L-lysine) Block Copolymer, Bioconjugate Chem., 1997, Vol. 8, No. 5, 702-707,	
		KATAYOSE et al., Remarkable Increasc in Nuclease Resistance of Plasmid DNA through Supramolecular Assembly with Poly(ethylene glycol)-Poly(L-lysine) Block Copolymer, Journal of Pharmaceutical Sciences, February 1998, Vol. 87, No. 2, 160-163.	
		KWOK et al., Strategies for maintaining the particle size of peptide DNA condensates following freeze-drying, International Journal of Pharmaceutics, 2000, Vol. 203, 81-88.	
		BEI et al., Lyophilization of Cationic Lipid-Protamine-DNA (LPD) Complexes, Journal of Pharmaceutical Sciences, March 2000, Vol. 89, No. 3, 355-364.	
		ALLISON et al., Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization, Journal of Pharmaceutical Sciences, May 2000, Vol. 89, No. 5, 682-691.	
		CORTESI et al., Effect of DNA Complexation and Freeze-Drying on the Physicochemical Characteristics of Cationic Liposomes, Antisense & Nucleic Acid Drug Development, 2000, Vol. 10, 205-215.	
V		PAXON et al., The Effect of Lyophilization on Plasmid DNA Activity, Pharmaceutical Development and Technology, 2000, Vol. 5, Issue 1, 115-122.	

	Examiner Signature	Dalh	Date Considered	1/7/03
•				

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

##3

PTO/SB/08A (08-00)

Approved for User rough 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

APPLICANT

First Named Inventor

Group Art Unit

 Complete if Known

 Application Number
 09/867,693

 Filing Date
 May 31, 2001

 First Named Inventor
 Mark J. Cooper

 Group Art Unit
 NOT YET ASSIGNED

 Examiner Name
 NOT YET ASSIGNED

 Attorney Docket Number
 03659.00009

SEP 2 (1 200)

**U.S. PATENT DOCUMENTS** U.S. Patent Document Date of Publication of Cited Document Pages, Columns, Lines, Where Relevant Name of Patentee or Applicant Cite No.1 of Cited Document Passages or Relevant Kind Code<sup>2</sup> Number Figures Appear MM-DD-YYYY (if known) 5,656,611 Kabanov et al. 08-12-1997

FOREIGN PATENT DOCUMENTS								
<b>5</b>	0'1-	For	eign Patent De	ocument	Name of Patentee	Date of Publication of	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Office <sup>3</sup>	Number <sup>4</sup>	Kind Code⁵ ( <i>if known</i> )	or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		<u> </u>		<u> </u>				
		<del>                                     </del>						
		+						_
		1						
		1						

Examiner Signature	(),	)M	Date Considered	1/7/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark hee if English language Translation is attached.